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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,977	01/08/2002	Peter Nash	C150.12.3E	8750

7590 07/28/2004

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,977	NASH ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/8/04 and 5/18/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

'Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/22/03; 9/30/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 are pending.

2. In view of the amendment filed 3/8/04 and 5/18/04, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method as set forth in claims 1, 3, 17 and 18. The instant claims are drawn to a method of reducing or eliminating the incidence of illnesses caused by *all* colony-forming illness-causing "immunogens" that adhere to the rumen or intestinal tracts of *any* food animals and the method of making antibody to all undisclosed colony-forming illness-causing immunogens.

The specification discloses only a method of reducing or eliminating the incidence of food borne illness in humans caused by the presence of *E coli, Listeria, Salmonella and Campylobacter* by inhibiting the ability of said bacteria to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the bacteria to multiply. The method comprises inoculating female chicken in or about to reach their egg laying age, with said bacteria, allowing a period of time sufficient to permit the production in the bird of the antibody to said bacteria, harvesting the eggs laid by the birds, separating the antibody-containing contents of the eggs from the shells, drying the separated antibody-containing contents of said eggs, distributing the resulting dried egg antibody uniformly through animal feed or water, supplying the resulting antibody-containing animal feed or water to food animals to prevent adherence of the targeted bacteria in the intestinal tract of the food animals.

Other than the specific immunogens mentioned above for the claimed method, there is insufficient written description about all "colony-forming illness-causing immunogens" that caused incidence of illnesses in humans for the claimed method.

Given that the specification discloses only four bacteria that caused food borne illness in humans, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that the examiner has erroneously construed the requirement of 35 USC to include any person skilled in the art to make and use the invention commensurate in scope with the claims (page 16). Applicants state that the specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attached themselves to their hosts. Page 12, lines 11-13. The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that the hen layers the unique lgY type immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies, page 10, lines 4-5. The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the binding of lgY immunogens to the illness-causing immunogens as more IgY immunogens are available to bind to the illness-causing immunogens. The albumin IgM and IgA immtmoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. Applicants have provided a representative number of species of colony-forming illness-causing immunogens to describe the genus identified by the terms target colony-forming illness-causing immunogens in meat. These immunogens are well known illness-causing

immunogens. The species of immunogens are identified as from a class consisting of *E coli*, *Listeria*, *Salmonella* and *Campylobacter*.

In response to applicants' assertion that the examiner has erroneously construed the requirement of 35 USC to include any person skilled in the art to make and use the invention commensurate in scope with the claims, it appears that applicants argue about the scope of enablement rather than written description requirement under 35 USC 112 first paragraph. The claims are rejected for written description under 35 USC 112 first paragraph.

The specification discloses only a method of reducing or eliminating the incidence of food borne illness in humans caused by the presence of *E coli, Listeria, Salmonella and Campylobacter* by inhibiting the ability of said bacteria to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the bacteria to multiply. The method comprises inoculating female chicken in or about to reach their egg laying age, with said bacteria, allowing a period of time sufficient to permit the production in the bird of the antibody to said bacteria, harvesting the eggs laid by the birds, separating the antibody-containing contents of the eggs from the shells, drying the separated antibody-containing contents of said eggs, distributing the resulting dried egg antibody uniformly through animal feed or water, supplying the resulting antibody-containing animal feed or water to food animals to prevent adherence of the targeted bacteria in the intestinal tract of the food animals. Other than the specific immunogens mentioned above for the claimed method, there is insufficient written description about all other "colony-forming illness-causing immunogens" in meat by inhibiting the ability of the undisclosed immunogens to adhere to the rumen or intestinal tracts of food animals to reduce the ability said immunogens to multiply.

In contrast to applicants' assertion that IgY immunoglobulins ...binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony-forming illness-causing immunogen in the intestinal tract of the animals, the specification on page 10, lines 3-5 discloses "once immunized the hen layers the unique IgY types immunoglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The *albumin* helps resistance to the whole egg preparations and helps protect the avian antibodies." There is a lack of a disclosure about the IgY immunoglobulins ...binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony-forming illness as claimed.

In response to applicants' statement that Applicants have provided a representative number of species of colony-forming illness-causing immunogens to describe the genus identified by the terms target colony-forming illness-causing immunogens in meat, the scope of the claims 1, 3, and 17-18 encompass a method for reducing or eliminating the incidence of illnesses in humans caused by the presence of *all* colony-forming illness-causing immunogens. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Adequate written description requires more than a mere statement that it is part of the invention.

The specification discloses only a method of reducing or eliminating the incidence of food borne illness in humans caused by the presence of *E coli, Listeria, Salmonella and Campylobacter* by inhibiting the ability of said bacteria to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the bacteria to multiply. The method comprises inoculating female chicken in or about to reach their egg laying age, with said bacteria, allowing a period of time sufficient to permit the production in the bird of the antibody to said bacteria, harvesting the eggs laid by the birds, separating the antibody-containing contents of the eggs from the shells, drying the separated antibody-containing contents of said eggs, distributing the resulting dried egg antibody uniformly through animal feed or water, supplying the resulting antibody-containing animal feed or water to food animals to prevent adherence of the targeted bacteria in the intestinal tract of the food animals. Other than the specific immunogens mentioned above for the claimed method, there is insufficient written description about all "colony-forming illness-causing immunogens" that caused incidence of illnesses in humans for the claimed method.

Given that the specification discloses only four bacteria that caused food borne illness in humans, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

5. The following new grounds of rejections are necessitated by the amendment filed 3/8/04 and 5/18/04.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-2, 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), US Pat No 6,086,878 (of record, July 2000, PTO 892), US Pat No 5,741,489 (of record, April 1998, PTO 892).

The '895 patent teaches a method of reducing the incidence of illnesses such as diarrhea, colibacillosis by the presence of colony-forming illness-causing immunogen such as *E coli* in food animal or livestock such as piglets or calves (See entire document, abstract, column 5, lines 1-7, in particular). The reference method comprises the steps of inoculating an egg laying female birds such as hen against a selected immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks to permit the production of antibody in the bird of antibody to the targeted immunogen (See column 5, lines 57-66, in particular), harvesting the eggs laid by the birds (See column 6, line 1-8, in particular), separating the antibody-containing contents such as the yolk and albumen or the overall ovum from the shells (See column 6, lines 8-10, in particular), drying the separated antibody-containing contents

of the eggs such as the yolk (See column 6, line 19-25, in particular), distributing the dried egg antibody product uniformly through an animal feed or food as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 1 differs from the teachings of the reference only in that the method wherein the antibody in the eggs including IgY immuoglublins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony forming illness-causing immunogen in the intestinal tract of the animals.

The claimed invention in claims 2 and 11 differs from the teachings of the reference only in that the method wherein the colony-forming illness causing immunogen is *Salmonella*.

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* that is responsible for samonella enteritidis, the reference microbial adherence inhibitor inhibits the adhesion of *Salamonella* to human intestinal cells (See abstract, and Materials and Methods, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent

teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made inoculating female chickens in or about to reach their egg laying age with the particular targeted colony-forming illness-causing immunogen such as *E coli* as taught by '895 patent or the Salmonella as taught by Sugita-Konishi *et al* to make chicken immunoglobulins that inhibit the adhere of said colony-forming illness-causing immunogen to intestinal cell as taught by Sugita-Konishi *et al,*separating and drying the enire content of the egg as taught by the '878 patent or the whole egg as taught by the '489 patent that include the IgY immunoglobulins from the yolk and the IgM and IgA immunoglubulins in the albumin as taught by Kaspers *et al,* supplying the resulting mixed dried egg antibody product uniformly throughout the animal feed as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal as taught by the '895 patent and Sugita-Konishi *et al* thereby reducing their ability to multiply. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* can inhibit the adhesion of *Salamonella* to human intestinal cells (See abstract, and Materials and Methods, in particular). The '878 patent teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular); egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food

borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that the numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to use applicant's method of using IgY, IgM and IgA immunoglubulins in the entire contents of eggs to bind the IgY immunoglobulins to illness causing immunogens to inhibit the ability of the immunogens to adhere to the intestinal tracts of animals. Claims 1, 2 and 5 define a method for reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness-causing immunogens by inhibiting the adherence of targeted colony-forming illness-causing immunogens in the intestinal tracts of live animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins. The IgY immunoglobulins bind to the colony-forming illness-causing immunogens which inhibits the ability of the colony-forming illness-causing immumogens to adhere to the intestinal tracts of the animals. The binding process of the IgY immunoglobulins is assisted and helped by the IgM and IgA immunoglobulins. This prevents growth and colonization of the immunogens in the intestinal tracts of the animals. The result is absence of the illness-causing immunogens in the feed lot and its contents and animal which can contaminate its meat (page 18). There are insufficient teachings of the above combined references and no evidence of a motivating force which would impel one skilled in the art to make and use the claimed method of reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness causing immunogens in meat. The numerous rejections of the claims

In response to applicant's argument that the numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to use applicant's method of using IgY, IgM and IgA immunoglubulins in the entire contents of eggs to bind the IgY immunoglobulins to illness causing immunogens, the numerous rejections merely reflect on the scope of the claimed invention. As for the use of the entire contents of the eggs that include IgY from the yolk, the IgM and IgA from the albumin in the claimed method, the secondary reference '878 patent teaches "there is no need to separate the yolk from the albumin, except to achieve high concentration of antibody (see col. 9, lines 62-65 of '878 patent). The entire content of the eggs would include the albumin which contains IgM and IgA as taught by Kaspers et al. The

secondary reference '489 patent teaches that whole egg antibodies are more resistant to degradation by gastric acidity as compared to purified IgY from the yolk (see col. 2, lines 36-39 of '489).

In contrast to applicant's argument that there is no motivation which would impel one skilled in the art to make and use the claimed method of reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness causing immunogens in meat, the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969).

9. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 1-2, 5 and 11 mentioned above and further in view of Pell *et al* (J Dairy Sci 80: 2673-2681, 1997; PTO 892).

The combined teachings of the '895 patent, Kaspers *et al,* Sugita-Konishi *et al,* the '878 patent and the '489 patent have been discussed supra.

The claimed invention in claims 2 and 8 differs from the teachings of the reference only that the method wherein the colony-forming illness-causing immunogen is *Listeria.*

Pell *et al* teach that pathogens (immunogens) such as *E Coli* O157:H7, *Listeria monocytogenes*, and *Salmonellas spp* are major problems for the swine and poultry industries and these microbes post potential threat to human health because many outbreaks have been traced to ground beef and some to raw milk in the case of *E Coli* (See page 2674, column 1, *E coli* 0157:H7, in particular). Pell *et al* further teach that more cow excreted *Listeria monocytogenes* during winter than summer and human infections have been associated with consumption of unpasteurized dairy products and healthy animals can be asymptomatic carriers (See page 2675,

column 2, L monocytogenes). Pell *et al* also teaches that *Salmonella typhi* is the organism that responsible for 45% of the forborne disease in which the gastroenteritis have been traced to foods of animal origin and the economic costs of salmonellosis have been estimated at close to $1 billion per year and that the problem has been exacerbated by increasing antimicrobial resistance among Salmonella spp. Serotypes (See page 2676, column 1, *Salmonella spp*, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the *E coli* immunogen as taught by the '895 patent or the Salmonella as taught by Sugita-Konishi *et al* for the immunogen such as *Listeria* as taught by Pell *et al* that post potential threat to human health because many outbreaks have been traced to meat in food animals where these immunogens adhere and multiply in the rumen or intestinal tracts of food animal such as piglets, calves and lambs. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Pell *et al* teach that pathogens (immunogens) such as *E coli* O157:H7, *Listeria monocytogenes*, *Salmonellas spp* are major problems for the swine and poultry industries; the economic costs of salmonellosis have been estimated at close to $1 billion per year and that the problem has been exacerbated by increasing antimicrobial resistance among *Salmonella spp*. Serotypes (See page 2676, column 1, *Salmonella spp*, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* can inhibit the adhesion of *Salamonella* to human intestinal cells (See abstract, and Materials and Methods, in particular). The '878 patent teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular); egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that the method is not a treatment or cure for an illness in humans or animals. The claims define a method for preventing the incidence of illness in humans caused by the presence of colony-forming illness causing immunogens in meat. Claims 5, 8, 11 and 14 specifically defines the illness-causing immunogens as *E coli* (claim 5), *Listeria* (claim 8), Salmonella (claim 11) and Campylobacter (claim 14). The yolk and albumin are mixed and dried to provide a dried egg antibody product. This product is feed to animals with animal feed. The IgY immunoglobulins bind to the immunogens to prevent adherence of the immunogen in the intestinal tracts of the animals. The binding is assisted and increased by the presence of the IgM and IgA immunoglobulins. The secondary references do not suggest applicant's method for prevent the incidence caused by the presence of colony-forming illness causing immunogens. Pimentel in the '489 patent is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. Pell et al discloses that pathogens such as *E coli* O157:H7, *listeria*, *monocytogenes* and *Salmonella* are major problems in the swine and poultry industries. These pathogens also are a potential threat to human health. Pell does not suggest applicant's method for prevent the incidence caused by the presence of colony-forming immunogens.

In response to applicant's arguments against the references individually, one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

10. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 1-2, 5 and 11 mentioned above and further in view of Adesiyun *et al* (Br Vet J 148(6): 547-56, 1992; PTO 892).

The combined teachings of the '895 patent, Kaspers *et al,* Sugita-Konishi *et al,* the '878 patent and the '489 patent have been discussed supra.

The claimed invention in claims 2 and 14 differs from the teachings of the combined references only in that the method wherein the colony-forming illness-causing immunogen is *Campylobacter.*

Adesiyun et al teach that *Campyloacter* bacteria causes diarrhea in animals. Piglets have the highest prevalence of campylobacters infection, follows by calves and lowest in lambs (See abstract, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the *E coli* immunogen as taught by the '895 patent or the Salmonella as taught by Sugita-Konishi *et al* for the *Campylobacter* as taught by Adesiyun that post potential threat to human health because many outbreaks have been traced to meat in food animals where these immunogens adhere and multiply in the rumen or intestinal tracts of food animal such as piglets, calves and lambs. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Adesiyun et al teach that *Campyloacter* bacteria causes diarrhea in food animals. Piglets have the highest prevalence of *campylobacters* infection, follows by calves and lowest in lambs (See abstract, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Sugita-Konishi *et al* teach a microbial adherence inhibitor such as IgY antibody obtained from hens immunized with a mixture of bacteria such as *Salamonella* can inhibit the adhesion of *Salamonella* to human intestinal cells (See abstract, and Materials and Methods, in particular). The '878 patent teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular); egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that the method is not a treatment or cure for an illness in humans or animals. The claims define a method for preventing the incidence of illness in humans caused by the presence of colony-forming illness causing immunogens in meat. Claims 5, 8, 11 and 14 specifically defines the illness-causing immunogens as *E coli* (claim 5), *Listeria* (claim 8), *Salmonella* (claim 11) and *Campylobacter* (claim 14). The yolk and albumin are mixed and dried to provide a dried egg antibody product. This product is feed to animals with animal feed. The IgY immunoglobulins bind to the immunogens to prevent adherence of the immunogen in the intestinal tracts of the animals. The binding is assisted and increased by the presence of the IgM and IgA immunoglobulins. The secondary references do not suggest applicant's method for prevent the incidence caused by the presence of colony-forming illness causing immunogens. Pimentel in the '489 patent is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. Pell et al discloses that pathogens such as *E coli* O157:H7, *listeria*, *monocytogenes* and *Salmonella* are major problems in the swine and poultry industries. These pathogens also are a potential threat to human health. Pell does not suggest applicant's method for prevent the incidence caused by the presence of colony-forming immunogens.

In response to applicant's arguments against the references individually, one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

11. Claims 3-4, 6-7, 12-13, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), Sugita-Konishi *et al* (of record, Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892), US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 1-2, 5 and 11 and further in view of US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Kaspers *et al,* Sugita-Konishi *et al,* the '878 patent and the '489 patent have been discussed supra.

The claimed invention in claims 3 and 6 differs from the combined teachings of the references only in that the method includes providing a dry feed carrier, coating the dry feed carrier with the separated antibody-containing contents of the eggs.

The claimed invention in claims 4 and 19 differs from the combined teachings of the references only in that the method wherein the immunogen is *E coli*, and *Salmonella*.

The claimed invention in claim 12 differs from the combined teachings of the references only in that the method includes providing a dry feed carrier, drying the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

The claimed invention in claims 7, 13 and 18 differs from the teachings of the reference only in that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The claimed invention in claim 17 differs from the teachings of the reference only in that the method includes coating the dry feed carrier material with the antibody-containing contents of said eggs, distributing said carrier material coated with the antibody-containing contents of said eggs substantially uniformly in animal feed and supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals.

The '878 patent further teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); As an example, the dried egg powder can be used in drinks, or protein supplement (See column 9, lines 47-8, in particular).

The '489 patent further teaches spray dried whole egg (See column 2, lines 36-39, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to spray dry or to coat any dry feed carrier such as soybean hulls, rice hulls

cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent or animal feed as taught by the '878 patent with the entire antibody-containing contents of the eggs that binds to immunogen such as *E coli* as taught by the '895 or *Salmonellas* as taught by Sugita-Konishi *et al and* substantially supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals as taught by the '895 patent, Kaspers *et al,* Sugita-Konishi *et al,* the '878 patent and the '489 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches that the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The mixing of dry feed carrier material such as soybean hulls coated with the separated entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that applicant coat a carrier material with the entire contents of the harvested eggs or dried egg antibody product which inhibits adherence of a colony-forming illness-causing immunogen to the intestinal tract of the animals. Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal portion or sprayed directly onto food pellet in oil. There is no suggestion in Betz et al in the '867 patent of a coating of an egg antibody product on animal feed carrier material.

However, the dry feed carrier soybean hulls (page 26 of specification) in the claimed invention is the same as animal feed soybean hulls as disclosed on page 27 of specification). Further, the mixing of dry feed carrier material such as soybean hulls coated with the separated

entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). In response to applicant's arguments against the references individually, one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

12. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892), and Pell *et al* (J Dairy Sci 80: 2673-2681, 1997; PTO 892) as applied to claim 8 mentioned above and further in view of US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The combined teachings of the '895 patent, Kaspers *et al,* the '878 patent, the '489 patent and Pell *et al* have been discussed supra.

The claimed invention in claim 9 differs from the combined teachings of the references only in that the method providing a dry feed carrier, coating the dry feed carrier with the separated antibody-containing contents of the eggs.

The claimed invention in claim 10 differs from the combined teachings of the references only in that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent further teaches hyperimmunized spray-dried egg powder can be mixed with food or animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); As an example, the dried egg powder can be used in drinks, or protein supplement (See column 9, lines 47-8, in particular).

The '489 patent further teaches spray dried whole egg (See column 2, lines 36-39, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to spray dry or to coat any dry feed carrier such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent or animal feed as taught by the '878 patent with the entire antibody-containing contents of the eggs that binds to *listeria* as taught by Pell *et al* and substantially supplying the resulting dry carrier material coated with the antibody containing contents of said eggs and animal feed to food animals to substantially prevent adherence of the immunogen in the rumen or intestinal tracts of the animals as taught by the '895 patent, Kaspers *et al,* the '878 patent, the '489 patent and Pell et al. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches that the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The mixing of dry feed carrier material such as soybean hulls coated with the separated entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

Applicants' arguments filed 3/8/04 and 5/18/04 have been fully considered but are not found persuasive.

Applicants' position is that applicant coat a carrier material with the entire contents of the harvested eggs or dried egg antibody product which inhibits adherence of a colony-forming

illness-causing immunogen to the intestinal tract of the animals. Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal portion or sprayed directly onto food pellet in oil. There is no suggestion in Betz et al in the '867 patent of a coating of an egg antibody product on animal feed carrier material.

However, the dry feed carrier soybean hulls (page 26 of specification) in the claimed invention is the same as animal feed soybean hulls as disclosed on page 27 of specification). Further, the mixing of dry feed carrier material such as soybean hulls coated with the separated entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). In response to applicant's arguments against the references individually, one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

13. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Adesiyun *et al* (Br Vet J 148(6): 547-56, 1992; PTO 892), Kaspers *et al* (Zentralbl Veterinarmed A 43(4): 225-31, abstract only, June 1996; PTO 892), US Pat No 6,086,878 (July 2000, PTO 892), US Pat No 5,741,489 (April 1998, PTO 892), and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The '895 patent teaches a method of reducing the incidence of illnesses such as diarrhea, colibacillosis by the presence of colony-forming illness-causing immunogen such as *E coli* in food animal or livestock such as piglets or calves (See entire document, abstract, column 5, lines 1-7, in particular). The reference method comprises the steps of inoculating an egg laying female birds such as hen against a selected immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), allowing a period of time such as a few weeks to permit the production of antibody in the bird of antibody to the targeted immunogen (See column 5, lines 57-66, in particular), harvesting the eggs laid by the birds (See column 6, line 1-8, in particular), separating

the antibody-containing contents such as the yolk and albumen or the overall ovum from the shells (See column 6, lines 8-10, in particular), drying the separated antibody-containing contents of the eggs such as the yolk (See column 6, line 19-25, in particular), distributing the dried egg antibody product uniformly through an animal feed or food as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 14 differs from the teachings of the reference only that the method differs from the teachings of the reference only in that the method wherein the antibody in the eggs including IgY immuoglublins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony forming illness-causing immunogen in the intestinal tract of the animals and wherein the colony-forming illness-causing immunogen is *Campylobacter* instead of *E coli.*

The claimed invention in claim 15 differs from the combined teachings of the references only in that the method includes providing a dry feed carrier, drying the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

The claimed invention in claim 16 differs from the teachings of the reference only in that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

Adesiyun *et al* teach that *Campyloacter* bacteria causes diarrhea in animals. Piglets have the highest prevalence of campylobacters infection, follows by calves and lowest in lambs (See abstract, in particular).

Kaspers *et al* teach IgG (IgY) is primary immunoglobulin isotype from the egg yolk while IgM and IgA are mainly found in the albumin (See abstract, in particular).

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers

sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E coli* that causes food borne illness onto enterocytes and reduces the bacteria from multiply in livestock such as piglets and calves (See column 2, liens 49-61, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made substitute the *E coli* as taught by the '895 patent for the *Campyloacter* bacteria as taught by Adesiyun *et al* by inoculating female chickens in or about to reach their egg laying age with said *Campyloacter* bacteria to make chicken immunoglobulins that inhibit the adherence of *Campyloacter* bacteria to intestinal cell as taught by '895 patent, separating and drying the enire content of the egg by coating a dry feed carrier such as soybean hulls, rice hulls as taught by the '867 patent with said antibody as taught by the '878 patent or the whole egg as taught by the '489 patent that include the IgY immunoglobulins from the yolk and the IgM and IgA immunoglubulins in the albumin as taught by Kaspers *et al, and* supplying the resulting mixed dried egg antibody product uniformly through an animal feed or food as an additive to

food for animal or animal feed or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal as taught by the '895 patent and Sugita-Konishi *et al* thereby reducing their ability to multiply. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '895 patent teaches that the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Adesiyun *et al* teach that *Campyloacter* bacteria causes diarrhea in animals and Piglets have the highest prevalence of campylobacters infection. The '878 patent teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The mixing of dry feed carrier material such as soybean hulls coated with the separated entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

Applicants' position is that applicant coat a carrier material with the entire contents of the harvested eggs or dried egg antibody product which inhibits adherence of a colony-forming illness-causing immunogen to the intestinal tract of the animals. Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal portion or sprayed directly onto food pellet in oil. There is no suggestion in Betz et al in the '867 patent of a coating of an egg antibody product on animal feed carrier material.

However, the dry feed carrier soybean hulls (page 26 of specification) in the claimed invention is the same as animal feed soybean hulls as disclosed on page 27 of specification). Further, the mixing of dry feed carrier material such as soybean hulls coated with the separated entire contents of the eggs uniformly in animal feed versus mixing dried egg antibody product onto the feed is an obvious variation of the reference teachings since the '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with animal feed rations or sprayed to coat directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

17. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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